

Remarks

Claims 19, 24, 33, 44, 55-65, and 71-77 have been canceled without prejudice or disclaimer. Claims 18, 22, 34, 43, 45-46, and 81 have been amended. No new matter has been added.

Claims 18, 22-23, 25-32, 34-43, 45-54, 66-70, and 78-84 are pending.

I. Rejections Under 35 U.S.C. § 112, First Paragraph**A. Written Description**

The Examiner has rejected claims 22-32, 55-65, and 71-77 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

In response, although Applicants disagree and maintain that the previously pending claims were fully supported in the specification, claim 22 has been amended to note that the encoded amino acid sequence consists of SEQ ID NO:56. Moreover, claims 24, 55-65, and 71-77 have been canceled without prejudice or disclaimer, thus obviating the rejection of such claims. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

B. Enablement

The Examiner has rejected claims 22-65 and 71-77 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Although the Examiner accepts that the specification enables "an isolated polynucleotide consisting of SEQ ID NO:55, specific fragments thereof, vectors and host cells consisting of these," the Examiner alleges that the specification does not enable "an isolated polynucleotide comprising SEQ ID NO:55, or a nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO:56 or epitope bearing portions thereof."

In response, although Applicants disagree and maintain that the previously pending claims were fully enabled, claims 22, 34, 43, and 45-46 have been amended to note that the encoded amino acid sequence consists of SEQ ID NO:56 or the specified portions, respectively. Moreover, claims 24, 33, 44, 55-65, and 71-77 have been canceled without prejudice or disclaimer, thus obviating the rejection of such claims. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

C. Alleged Improper Incorporation by Reference

Applicants note that the Examiner has asserted that U.S. Provisional App. No. 60/029,960 is "improperly incorporated by reference" on page 9 of the specification. Office Action at page 5.

Applicants respectfully disagree, and maintain that the entire contents of U.S. Provisional App. No. 60/029,960, including the sequences therein, were properly incorporated by reference into the present application. In particular, the specification clearly states that, "A more complete listing of the sequence obtained from the *S. pneumoniae* genome may be found in co-pending U.S. Provisional Application Serial No. 60/029,960, filed 10/31/96, incorporated herein by reference in its entirety." As noted in M.P.E.P. § 2163.07(b), "The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." To the extent that the Examiner is alleging that certain subject matter is essential, Applicants respectfully request that the Examiner identify such subject matter, so that Applicants may either provide a copy of the referenced material and an affidavit, or an amendment to the specification and an affidavit, as required for essential subject matter by M.P.E.P. § 608.01(p).

In light of the above, Applicants respectfully request that the Examiner clarify the propriety of the incorporation by reference of the '960 Application.

II. Rejections Under 35 U.S.C. § 112, Second Paragraph

A. Claim 25

The Examiner has rejected claim 25 as allegedly containing a misspelling of the term "polynucleotide." In response, Applicants note that the document containing claim 25 (faxed to the Office on August 6, 2003) contains the correct spelling of the term; it appears that the facsimile received by the Office contains a smudge or other printing error. Nevertheless, the version of claim 25 contained herein does not contain the misspelling, thus obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Applicants note that the present claim 25 has not been marked up to show a change, as the previously pending version did not have the misspelling. Should the

Examiner disagree, Applicants will be glad to provide a copy of the previous correspondence together with the Certificate of Transmission as evidence thereof.

B. Claims 55-65

The Examiner has rejected claims 55-65 as allegedly indefinite. Claims 55-65 have been canceled without prejudice or disclaimer, thus obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

C. Claim 81

The Examiner has rejected claim 81 as allegedly indefinite for "the use of comprising language because it is in conflict with the closed language of the independent claim from which it depends."

In response, claim 81 has been amended herein to replace the comprising language with "which is fused to," similar to claims 25, 35, 47, and 67, thus obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

III. Rejections for Alleged Double Patenting

A. U.S. Patent No. 6,420,135

The Examiner has rejected claims 22-84 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-14, 21, 31, 40, 50, and 55-76 of U.S. Patent No. 6,420,135.

Although Applicants do not acquiesce with the instant rejection, in the interest of facilitating prosecution, Applicants have submitted herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c), thereby obviating the instant rejection. Accordingly, Applicants respectfully request that the obviousness-type double patenting rejection be reconsidered and withdrawn.

B. Provisional Rejections

The Examiner has provisionally rejected claims 33-45 and 47-65 under the judicially created doctrine of obviousness-type double patenting as allegedly being

unpatentable over claims 35-47 of U.S. App. No. 09/765,272 or all the claims of the corresponding U.S. Pub. No. 2002/0061545 A1, and over all the claims of U.S. App. No. 10/158,844 and corresponding U.S. Pub. No. 2004/0029118 A1.

Applicants note that claims 36-39 of the '272 Application were canceled, and that claim 35 was amended to remove Ile-175 to Asp-181 of SEQ ID NO:66; claim 35 now recites Pro-329 to Glu-364 of SEQ ID NO:66. Thus, the provisional rejection no longer applies with respect to the allowed claims of the '272 Application (corresponding to the 2002/0061545 publication).

With respect to the '844 Application (corresponding to the 2004/0029118 publication), the Examiner has not explained a specific basis for the provisional rejection. Moreover, Applicants note that the pending claims of the '844 Application are directed to, *inter alia*, nucleotides 5548 to 8121 of SEQ ID NO:94, which are outside of the overlap identified by the Examiner in the rejection for U.S. Patent No. 6,420,135. Accordingly, Applicants believe that the provisional double patenting rejection is incorrect, and should be reconsidered and withdrawn.

However, should the Examiner maintain one or both provisional rejections after consideration of the above, Applicants defer addressing them further until the '272 or '844 application is parented. *See, e.g.*, M.P.E.P. 1504.06.

IV. Rejection Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 33, 43, and 47-54 under 35 U.S.C. § 102(e) over U.S. Patent No. 5,534,410.

In response, Applicants note that the '410 Patent does not identify residues 249-257 as an epitope. Nevertheless, claim 33 has been canceled without prejudice or disclaimer, and claim 43 has been amended to incorporate the subject matter of previous claim 44, thus obviating the rejection. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is

invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the issuance of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: August 20, 2004

Respectfully submitted,

By 

Mark J. Hyman

Registration No.: 46,789

HUMAN GENOME SCIENCES, INC.

Intellectual Property Dept.

14200 Shady Grove Road

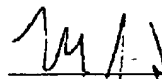
Rockville, Maryland 20850

(240) 314-1224

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

1. Fax Cover Sheet
2. Fee Transmittal Sheet
3. Petition for Extension of Time
4. Amendment and Reply Under 37 C.F.R. § 1.111
5. Terminal Disclaimer

I hereby certify that the above-listed correspondence is being facsimile transmitted to the United States Patent and Trademark Office on August 20, 2004.



Mark J. Hyman

Registration No.: 46,789

HUMAN GENOME SCIENCES, INC.

Intellectual Property Dept.

14200 Shady Grove Road

Rockville, Maryland 20850

(240) 314-1224